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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KUDLA, JOSEPH S	
ART UNIT	**PAPER NUMBER**
1611	

MAIL DATE	DELIVERY MODE
02/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,423	DURANTON	
	Examiner	Art Unit	
	Joseph S. Kudla	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *14, 16-18, 22-38 and 42-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,15,19-21,26 and 39-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 December 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :5/20/05, 8/22/05, 8/07/07 and 12/28/07.

DETAILED ACTION

Priority

1. This application is the U.S. National Phase of International Application PCT/FR03/001919, filed on June 23, 2003 and claims priority to French Application Nos. 02/07763, 02/07764 and 02/7765, filed June 21, 2002. Priority is acknowledged.

2. It is noted that this application appears to claim subject matter disclosed in U.S. National Phase of International Application PCT/FR03/001919, filed on June 23, 2003 and claims priority to France Application Nos. 02/07763, 02/07764 and 02/7765, filed June 21, 2002. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the

pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge

under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Election/Restrictions

3. Applicant's election with traverse of Group I: a composition comprising taurine and/or hypotaurine and/or salts thereof that are acceptable in an oral composition, for the preparation of an oral composition that is useful for treating and preventing aging of the pilosebaceous unit and/or alopecia in the reply filed on November 13, 2007 is acknowledged. The traversal is on the ground(s) that the patent office has required the restriction between Groups I and III (page 7, paragraph 2 of Applicant's November 13, 2007 reply). This is not found persuasive because the restriction was based on the lack of unity that existed between claims 1 and 16. Claim 1 is a composition comprising taurine and/or hypotaurine and/or salts thereof that are acceptable in an oral composition that is useful for treating and preventing aging of the pilosebaceous unit and/or alopecia; whereas, claim 16 discloses a composition comprising polyphenol(s) and/or of fatty acid(s) and also esters thereof, and mixtures thereof, and/or of an extract comprising the same, for the preparation of an oral composition that is useful for treating or preventing disorders of the pilosebaceous unit.

PCT Rule 13.2 states:

> Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled **only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.** The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Claims 1 and 16 do not share a special technical feature, therefore; the claims lack unity.

The requirement is still deemed proper and is therefore made FINAL.

4. The restriction between Groups I and VI (original claims 39-41) was vacated in a telephone conversation with Applicant's representative on October 17, 2007 in exchange for the election of a genus in original claim 41. Applicant chose the genus polyphenols.

Applicant's November 13, 2007 correspondence elects Group I which encompasses amended claims 1-15, 19-26 and 41 and original claims 39 and 40. The inventions contained in group II-V and VII are withdrawn from consideration as being drawn to non-elected subject matter - See 37 CFR 1.142(b) (original claims 16-18, 27-28 and 42-43). Claim numbers 14 and 22-25 are withdrawn from consideration as being drawn to non-elected subject matter see 37 CFR 1.142(b). Accordingly, the subject matter now under consideration is drawn to claims 1-13, 15, 19-21, 26 and 39-41.

Information Disclosure Statement

5. The Information Disclosure Sheet (IDS) correspondence submitted by Applicant on May 20, 2005, August 22, 2005, August 7, 2007 and December 28, 2007 are acknowledged and have been reviewed to the extent each is a proper citation on a US Patent and has been supplied.

6. The information disclosure statement filed May 20, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specifically, the WIPO document WO02/24189 and KR 2002 041 348 have not been provided.

7. The information disclosure statement filed on February 10, 2005 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because several of the referenced documents are presented only in the French or German language without an English translation. Specifically, documents FR 2 734 477, FR 2 581 542, EP 0 064 012, EP 0 353 123, EP 0 356 271, EP 0 408 442, EP 0 522 964, EP 0 420 707, EP 0 459 890 and EP 0 519 819 are in French and DE 202 04 844 is in German. They have been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of

any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Abstract

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

8. The abstract of the disclosure is objected to because the length (47 words including a redundant phrase) of the narrative describing the invention is too short in length to accurately convey Applicant's invention. Correction is required. See MPEP § 608.01(b).

9. The abstract of the disclosure is objected to because of the word "usef" on line 2 and "ageing" on line3 are misspelled. The Examiner believes the Applicant intended to state "useful" and "aging." Correction is required. See MPEP § 608.01(b).

10. The abstract of the disclosure is objected to because the phrase "in an oral composition for the preparation of an oral composition" is redundant. Correction is required. See MPEP § 608.01(b).

Specification

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.

(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Content of Specification

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).

(e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

(f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the

field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

(l) Sequence Listing, See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

11. The specification of a utility application should include the above sections in order. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading. Specifically, none of the section headings or a disclosure of joint research agreements or a cross-reference to related applications are present.

Appropriate action is required.

Drawings

12. The drawings are objected to because Figures 1 and 2 do not contain labels for the abscissa. In addition, the symbols for the two lines in each figure are indistinguishable and no labeling is present. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

13. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "square" has been used to designate both the active agent and the vehicle making the two lines indistinguishable. The abscissa should be in

months. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-13, 15, 19-21, 26 and 39-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide adequate written description for the term "aging." The term "aging" is not adequately defined. Applicant has failed to provide any disclosure as to what Applicants contemplate "aging" is. In the normal art context, "aging" could simply mean a reference point at a later date from a previous reference point, or a change in an organism over time. By this standard, claims 1-13, 15, 19-21, 26 and 39-41 incorrectly imply or indicate that any aging of pilosebaceous unit may result in the rigidification of the connective sheath, excessive crosslinking of natural collagens and miniaturization of the hair follicle which results in hair loss (e.g., alopecia). As indicated by Applicant at page 1, line 30 to page 2, line 3, alopecia and "aging" of the pilosebaceous unit is actually the result of physical and chemical changes that result in functional disorders in the pilosebaceous unit and has nothing to do with the "age" of the pilosebaceous unit. None of the indications are a result of aging, but the indications have a greater preponderance to occur in an "aged" subject.

15. Claims 1-13, 15, 19-21, 26 and 39-41are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for:

a) the prevention of aging of the pilosebaceous unit and/or alopecia comprising administering to a human being an oral composition of taurine and/or hypotaurine or their salts;

b) the reducing or preventing impairment of the connective tissue of the hair follicle;

c) the reducing or preventing impairment of the hair follicle induced by rigidification of the connective sheath;

d) the reducing or preventing impairment of the hair follicle induced by excessive crosslinking and/or synthesis of natural collagens;

e) the regulation of metabolism and structure of collagens in perifollicular skin tissue;

f) the regulation of metabolism and structure of collagens in the connective sheath of the hair follicle;

g) the prevention of miniaturization of the hair follicle;

and

h) the dosage administration amounts effective for the treatment.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims without undue experimentation to treat diseases of the circulatory system.

Undue experimentation is a conclusion reached by weighing the noted factual considerations set forth below as seen in *In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)*. A conclusion of lack of enablement means that, based on the evidence regarding a fair evaluation of an appropriate combination of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without

undue experimentation.

These factors include:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

The breadth of the instant claims is extremely broad in scope for the types of conditions that can be prevented or treated with the composition of taurine and/or hypotaurine or their salts. Applicant has not provided sufficient evidence to support a claim set drawn to preventing or treating aging of the pilosebaceous unit and/or alopecia outlined in the instant claim set with the composition having taurine and/or hypotaurine or their salts. The breadth of the claims exacerbates the complex nature of the subject matter to which the present claims are directed.

The nature of the invention

The instant claim set outlines an invention that prevents or treats aging of the pilosebaceous unit and/or alopecia with a composition of taurine and/or hypotaurine or their salts. The instant claim set additionally outlines that the composition of taurine and/or hypotaurine or their salts can be used in conjunction with polyphenols. The claims disclose that the oral composition can be administered as a food supplement and the ranges for daily dosages to be administered.

The state of the prior art

Prior art in the field shows it is known that taurine has been used in topical administration for hair growth (Japanese Patent JP A 11-292753 and cited by applicant) and as a common ingredient in pet food for the treatment of hair loss and coat quality. However, the prior art is silent on the ability an oral formulation of taurine and/or hypotaurine or their salts to treat or prevent aging of the pilosebaceous unit and/or alopecia.

The level of predictability in the art

The instant claimed invention is highly unpredictable. Due to the general unpredictability in the pharmaceutical art and the lack of prior art showing the effects of taurine and/or hypotaurine or their salts on the aging of the pilosebaceous unit and/or alopecia, Applicant would need to show evidence of the likelihood that the taurine

and/or hypotaurine or their salts would have the desired physiological response through examples or scholarly discussion showing the nexus between what is commonly known in the art and that which Applicant asserts is his invention. In this particular case, the taurine and/or hypotaurine or their salts is required to be assessed for physiological activity by *in vivo* screening to determine if the taurine and/or hypotaurine or their salts exhibits the desired pharmacological activity of treating or preventing the aging of the pilosebaceous unit and/or alopecia. One study (Example 26, page 41) was performed by Applicant in which 72 women were given either a taurine/green tea/grape seed extract/zinc formulation or a placebo. The measure of success for the study, for which the criteria for inclusion were subjects having fine, lifeless and sebborrheic hair (page 41, lines 7-8), was self evaluation of the number of hairs present on a comb cast through the hair at t = 0 months, 3 months and 6 months. No studies were conducted with hypotaurine or a combination of taurine and hypotaurine. The prior art is silent and the discussion by Applicant to the feasibility of an oral formulation of taurine and/or hypotaurine or their salts to treat or prevent aging of the pilosebaceous unit and/or alopecia leads one of ordinary skill in the art to believe the invention is speculation. Applicant provides no correlation of the administration of an oral formulation of taurine and/or hypotaurine or their salts compared to the impairment of the connective tissue of the hair follicle, the impairment of the hair follicle due to excessive crosslinking and/or synthesis of natural collagens, the impairment of the hair follicle induced by rigidification of the connective sheath, the regulation of metabolism and structure of collagens in the perifollicular skin tissue, the regulation of metabolism and structure of collagens in the

connective sheath of the hair follicle and the prevention of miniaturization of the hair follicle. Therefore, one cannot predict the ability of the composition to elicit *any* pharmacological response, because the results were neither exemplified in Applicants' specification nor shown in the prior art. In addition, one of ordinary skill in the art cannot predict if an oral formulation of taurine and/or hypotaurine or their salts is effective for hair loss. The only study involving a taurine compound, specifically taurine, involved human subjects that were not known to have any of the indications Applicant is claiming (alopecia or the functional disorders of the pilosebaceous unit) in the instant claims. Subjects were not assessed as to their stress levels (e.g. life altering events); any hormonal imbalances (e.g. pregnancy) and their health (e.g. illnesses, diseases and drug use), as well as, the environmental conditions were not reported (e.g. chemical stresses, time of year, etc.). All of these parameters would have had a significant result on the study. In addition, the study participants were not in a clinical setting. Study participants were asked to self evaluate the number of hairs over the duration of the study. Parameters assessed in the study are not adequate to support *any* of Applicants' instant claims and one cannot predict with any certainty if an oral formulation of taurine and/or hypotaurine or their salts is effective for alopecia or the functional disorders of the pilosebaceous unit.

Applicant is reminded of the decision *Genentech Inc. vs. NovaNordisk* which states, " [A] patent is not a hunting license. It is not a reward for a search but a compensation for its successful conclusion and 'patent protection' is granted in return

for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" (42 USPQ 2d 1001, Fed. Circuit 1997).

In addition, to prevent, as defined by Merriam-Webster Dictionary is to keep from happening or existing, which implies taking advance measures against something possible or probable. Furthermore, the definition of "to prevent" and the "act of preventing" embraces the complete 100% inhibition. Thus, the burden of enablement in the assertion of this claim is much higher than would be the case of enabling the treatment of the condition and is not achieved. Nowhere in the prior art or instant application have the compounds in the instant claim set been enabled to prevent or treat the aging of the pilosebaceous unit and/or alopecia.

The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen for the treatment of aging of the pilosebaceous unit and/or alopecia on its face. *In re Fisher, 427 F. 2d, 833, 166 USPQ 18 (CCPA 1970)*, indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Hence, one of skill in the art is unable to fully predict the ability of an oral formulation of taurine and/or hypotaurine or their salts to prevent or treat the aging of the pilosebaceous unit and/or alopecia.

The amount of direction provided by the inventor and the existence of working examples

The instant specification does not provide adequate guidance, which would allow the skilled artisan to extrapolate from the disclosure and examples provided, to practice the claimed methods commensurate in the scope with the instant claims. Applicant provides *no* guidance using an oral formulation of taurine and hypotaurine or their salts as specified in instant claim 1, *no* guidance demonstrating the ability of an oral formulation of taurine and/or hypotaurine or their salts to prevent or treat the aging of the pilosebaceous unit and/or alopecia, *no* guidance demonstrating the restoration of hair loss within adequate control/study measures and *no* guidance demonstrating the arrival of a dosage level effective for treating or preventing the aging of the pilosebaceous unit and/or alopecia. Adequate enablement requires more than a mere statement that a compound treats a given condition.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention (*In re Wright, 999 F. 2d 1557, 1562; 27 USPQ 2d 1510, 1514 (Fed. Cir. 1993)*). The specification lacks sufficient disclosure to support applicant's claims of a method for treating or preventing the aging of the pilosebaceous unit and/or alopecia with an oral formulation of taurine and/or hypotaurine or their salts. There is not seen sufficient working examples or data from references in the prior art providing a nexus between that which applicant asserts is supporting a method of treating or preventing the aging of the pilosebaceous unit and/or

alopecia with an oral formulation of taurine and/or hypotaurine or their salts and the amount of disclosure Applicant has actually provided.

The quantity of experimentation needed to make and use the invention based on the content of the disclosure

Based on the unpredictable nature of the invention, the state of the prior art and the breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation. The essential element towards the validation of a therapeutic modality capable of performing the mechanism of action is the ability to test the compound within *specific parameters* in advance of administration of a compound and, while maintaining experimental control, link those results with sampling time points. Once it can be documented that the compound of interest elicits a desired pharmacological response within experimental controls, the compound, for the sake of this forum, could generally be assumed to have that pharmacological activity.

Based on the unpredictable nature of the invention, the state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

16. Claims 1-13, 15, 19-21, 26 and 39-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "aging" is a relative term which renders the claim indefinite. The term "aging" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The language "from about 0.5" in line 2 of claim 21 is indefinite. The assumption is that "from about" represents a range. Conceivably, the range extends to 0.0 mg/day of polyphenols, which negates the polyphenols in the claim and leaves the Examiner to question the meaning of the invention Applicant claims, thereby rendering the subject matter of the instant claim unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 1 and 39 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kisters et al. (US Patent Number 6,331,569 and cited by Applicant).

Kisters et al. teach a combination product that is useful in improving quantitative and qualitative hair growth and can be administered orally (Abstract). Kisters et al. also teach that the invention can be a dietetic preparation (column 1, line 9) useful in the treatment of alopecia (column 2, lines 31-34). Kisters et al. teach the combination

product contains taurine (Example 2, column 5, line 50 to column 6, line 15). The open language of the instant claims allows the inclusion of any number of additional active or inert ingredients.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 1-13, 15, 19-21, 26 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Otsu et al. (US Patent number 5,582,817), in view of Duranton et al. (WIPO Application number WO 2004/034820).

Otsu et al. teach the use of an oral formulation of a zinc salt of amino acids (column 6, lines 30-33 and Abstract), specifically taurine (column 4, line 36) in the treatment of alopecia (column 30, line 4). Otsu et al. teach the oral formulation can be administered as a food supplement (e.g., vitamin) (column 7, line 10). The composition is intended for human and animal usage (column 6, lines 48-58).

Otsu et al. does not teach the use of polyphenols for the treatment or prevention of aging of the pilosebaceous unit and/or alopecia or the ranges useful for administration.

Duranton et al. teach the use of an oral formulation of polyphenols (e.g., flavinoids) to prevent or treat the functional disorders of the pilosebaceous unit or alopecia in humans (Abstract). The oral formulation is a food supplement (Abstract).

It would have been obvious to one of ordinary skill in the art in view of the teachings of Otsu et al., drawn to an oral formulation of a zinc salt of amino acids, specifically taurine, in the treatment of alopecia, and Duranton et al. drawn to an oral formulation of polyphenols (e.g., flavinoids) to prevent or treat the functional disorders of the pilosebaceous unit or alopecia in mammals, a preparation of all of the elements of both formulations would similarly be useful in treating alopecia. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-

dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.).

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.). Therefore, no more than routine experimentation would have been necessary to one of ordinary skill in the art to be able to arrive at the administration unit dosages recited in instant claims 8-10, 20-21 and 40.

Therefore, the teachings of Otsu et al., in view of Duranton et al. render the claimed invention obvious.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Kudla whose telephone number is (571) 270-3288. The examiner can normally be reached on 9am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JK

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER

1/30/08